



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

NOV 6 2002

Daniel A. Kravoc  
Counsel to Lona Inc.  
Patton Boggs LLP Attorneys at Law  
2550 M Street, NW  
Washington, DC 20037-1350

Re: Docket No. 75N-183H/CP14

Dear Mr. Kravoc:

This is in reference to your citizen petition (CP14) dated May 15, 2002, filed under Docket No. 75N-183H in the Dockets Management Branch. The petition requests that FDA reopen the administrative record to allow for the submission and evaluation of additional data supporting the safety and efficacy of benzethonium chloride in topical antimicrobial drug products for over-the counter (OTC) healthcare professional and consumer use.

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR 10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, agency resources and priorities permitting. See 21 CFR 10.30(e). This is to advise you, pursuant to 21 CFR 10.30(e)(2), that because of the existence of other priorities, the agency is unable to provide a response to the petition at this time.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

Janet Woodcock, M.D.  
Director  
Center for Drug Evaluation and Research

75N-183H

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 11-6-02

FROM: Director  
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 75N-183H

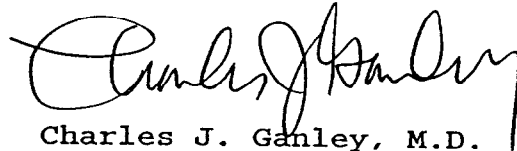
TO: Dockets Management Branch, HFA-305



The attached material should be placed on public display under the above referenced Docket No.



This material should be cross-referenced to Comment No. CP14



Charles J. Ganley, M.D.

Attachment